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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/702,039	NIESWANDT, BERNHARD	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *7 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 9-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.00

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 5/12/05, is acknowledged.

2. Claims 1-13 are pending.

3. Claims 7-8 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

4. Claims1-6 and 9-13 are under examination as they read on a medicament for protection against thrombotic diseases as it reads on an antibody JAQI and a hybridoma and a method of producing.

5. Claims 4-5 and 13 are objected to under 37 CFR § 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Claim 11 is objected to because the word "wherein" should be "comprises".

6. In view of the amendment filed on 5/12/05, only the following rejections are remained.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> *The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

8. Claims 1-6 and 9-13 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the **hybridoma DSM ACC 2487 that produce the JAQ1 antibody,** recited in claims 3, 5-6, 9-10 and 13, is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, a deposit of the hybridoma, which produces this antibody, may satisfy first paragraph. See 37 CFR 1.801-1.809.

The declaration filed by Applicant's counsel Dr. Hug Pfeil submitted on 5/12/05 is insufficient to overcome the issue of deposit of Biological material because the declaration refers to a bacteria in point 2, however, the deposit is a hybridoma that produce the antibody JAQ1. Further, said declaration refers to the attached deposit receipt in point 4, however, no such attachment is found. Finally, it is noted that the declaration is made under 608.01(p) C, however, MPEP 608.01(p) deals with Completeness rather than biological deposits.

Further the specification does not reasonably provide enablement for **any medicament** for protection against thrombotic diseases characterized in that it comprises at least one **active principle** that induces an irreversible inactivation or degradation of any **collagen receptor on thrombocytes** in claim 1; which characterized in that an antibody induces an irreversible inactivation or degradation of a collagen receptor on thrombocytes in claim 2, characterized in that it comprises the monoclonal antibody JAQ1 in claim 3, characterized in that it contains an antibody against the thromobocyte collagen receptor GPVI in claim 4, characterized in that it contains the humanized monoclonal antibody JAQ1 in claim 5, or a diagnostic agent for the determination of the expression rate of the collagen receptor GPVI, characterized in that it contains a labeled monoclonal or polyclonal antibody directed against the GPVI epitope, preferably as defined by JAQ1 in claim 6, or a monoclonal antibody, characterized in that it binds to the "same or similar epitope of the collagen receptor" for thrombocytes as the monoclonal antibody JAQ1 in claim 10, a method of preparing a medicament against thrombotic diseases, wherein an active principle that induces an irreversible inactivation or degradation of a collagen receptor on thrombocytes is combined with a pharmaceutically acceptable carrier in claim 11, wherein the active principle is a monoclonal antibody in claim 12, wherein the active principle is the monoclonal antibody JAQ1 in claim 13. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the same reasons set forth in the previous Office Action mailed 11/17/04.

Applicant's arguments, filed 5/12/05, have been fully considered, but have not been found convincing.

Applicant submits that the specification should be interpreted in light of what was known in the art at the time of filing. Applicant draws the Examiner's attention to Nieswandt et al (IDS Ref. 15) to demonstrate how JAQ1 mAb was prepared. Further, Applicant notes that Nieswandt et al reference was used as art against the claimed invention and concluded that the specification is enabled for claims 1-6 and 9-13.

While the examiner agrees with applicant's conclusion that the JAQ1 mAb and a method of making said antibody is enabled. However, the claimed invention is drawn broadly to any medicament comprises any active principle and a method of making said active principle, rather than JAQ1 mAb.

Applicant asserts that Schulte's speculation as to the existence of second GPVI-independent receptor, is merely one more possible example of a collagen receptor that may be targeted by the active principle of claim 1. Applicant contends that though applicant need not specify exactly which collagen receptors the active principle of claim 1 acts on, the specification does mention several in addition to Schulte's proposed GPVI-independent receptor. Applicant refers to the specification on page 1, lines 25-28. Applicant submits that methods for determining whether a receptor has been inactivated or degraded are known in the art and used in the specification. Applicant concluded that the skilled artisan can readily adapt these methods to analyzing the expression of another collagen receptor.

However, the specification does not provide any guidance with respect to the activity of the targeted collagen receptor, nor any working examples. One skilled in the art would first have to determine the activity of the collagen receptor in order to develop the claimed active principle. Further, any assay for finding a product is not equivalent to a positive recitation of how to make a product. The claims fail to meet the enablement requirement for the "how to make" prong of 35 U.S. C. 112, first paragraph. The specification fails to disclose any particular structure for the claimed receptor antagonist, besides the mAb JAQ1. The specification does not provide any guidance or any working examples in this unpredictable art in view of Schulte's teachings, and thus the artisan would have been unable to prepare the active principle.

Applicant further submits that the specification discloses on page 13, lines 32-34 that the JAQ1 monoclonal antibody recognizes an epitope that is identical to or close to the CRP binding site on the GPVI receptor. Further applicant submits that with that level of guidance, it would not require undue experimentation for the skilled artisan to determine the exact epitope that the JAQ1 monoclonal antibody binds to, and thus, one example of such an epitope. Moreover, the skilled artisan could use, for example, competition experiments to determine whether a new antibody binds the same epitope or a similar epitope to that bound by JAQ1. Applicant submits that if the new antibody prevents labeled JAQ1 from binding to a target protein like GPVI, then the new antibody may bind the same or a similar epitope.

Again, the examiner agrees with applicant's assertion that the JAQ1 mAb and a method of making said antibody is enabled. However, the claimed invention is drawn broadly to any medicament comprises any active principle and a method of making said active principle, rather than JAQ1 mAb.

9. Claims 1-6 and 10-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons set forth in the previous Office Action mailed 11/17/04.

Applicant's arguments, filed 5/12/05, have been fully considered, but have not been found convincing.

Applicant is in possession of a composition comprising anti-GPVI antibody and JAQ1 antibody which specifically binds GPVI for reducing the platelet adhesion to collagen at sites of vascular injury.

Applicant is not in possession of any medicament for protection against thrombotic diseases characterized in that it comprises at least one active principle that induces an irreversible inactivation or degradation of any collagen receptor on thrombocytes in claim 1; which

characterized in that an antibody induces an irreversible inactivation or degradation of a collagen receptor on thrombocytes in claim 2, characterized in that it comprises the monoclonal antibody JAQ1 in claim 3, characterized in that it contains an antibody against the thromobocyte collagen receptor GPVI in claim 4, characterized in that it contains the humanized monoclonal antibody JAQ1 in claim 5, or a diagnostic agent for the determination of the expression rate of the collagen receptor GPVI, characterized in that it contains a labeled monoclonal or polyclonal antibody directed against the GPVI epitope, preferably as defined by JAQ1 in claim 6, or a monoclonal antibody, characterized in that it binds to the "same or similar epitope of the collagen receptor" for thrombocytes as the monoclonal antibody JAQ1 in claim 10, use of the active principle that induces an irreversible inactivation or degration of a collagen receptor on thrombocytes for the preparation of a medicament against thrombotic diseases in claim 11, wherein the active principle is a monoclonal antibody in claim 12, wherein the active principle is the monoclonal antibody JAQ1 in claim 13.

Applicant submits that the JAQ1 MAb is only one example of the claimed invention. Applicant identified several characteristics of this mAb, among tem, (1) that this antibody could bind to the GPVI collagen receptor, (2) that this antibody also mediated the inactivation of the receptor or degradation of the receptor such that the receptor was removed from thrombocytes, and (3) that the antibody could protect mice from death due to thrombosis due to cardiac arrest. Applicant submits that in identifying these properties, Applicant also recognized the broader concept of an agent that could interfere with a collagen recepto's ability to cause a thrombotic disease by inactivating that collagen receptor or causing it to be degraded or depleted from a thrombocyte's surface.

However, while the specification does provide an adequate written description of the JAQ1 mAb, there is no disclosure of the activity of any active principle that induces an irreversible inactivation or degradation of any collagen receptor on thrombodcytes, nor any method for analyzing such active principle or receptor. There is no structural characteristics of such active principle are provided, nor is there any indication that the applicant had possession of any active principle, besides JAQ1 mAb. One skilled in the art would conclude that the inventor was nto in possession of the claimed invention, the claim fails to comply with the written description requirement.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e2) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1-4 and 9-13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nieswandt *et al* (IDS ref No. C5) (J Biol Chem. 275(31):23998-4002, 2000) for the same reasons set forth in the previous Office Action mailed 11/17/04.

Applicant's arguments, filed 5/12/05, have been fully considered, but have not been found convincing.

Applicant argues that the instant application has an effective U.S. filing date of 1/23/01. Under 35 U.S.C 102(b), the invention must be "described in a printed publication in the U.S or a foreign country ...more than one year prior to the date of the application for patent in the U.S.. Applicant submits that the cutoff date for 102(b) purposes would be 1/23/00. Applicant submits that Nieswandt reference was published on 8/4/00, after the cutoff date.

However, the cutoff date is based on 1-year time, which is measured from the U.S. filing date (i.e., 01/22/2002) rather than a foreign filing date (i.e., 01/23/03). Applicant is reminded that a rejection under 35 U.S.C. 102(b) cannot be overcome by foreign priority dates, outside the 1-year grace period measured from the U.S. filing date.

12. Claims 1-2, 4 and 11 stand rejected under 35 U.S.C. 102(b) as being anticipated by Clemetson *et al* (IDS ref No. C3) (J Biol Chem. 274(41):29019-24, 1999), as is evidenced by Schulte et al (Blood, 15 May 2003, Vol. 101, No. 10, pp. 3948-3952) for the same reasons set forth in the previous Office Action mailed 11/17/04.

Applicant's arguments, filed 5/12/05, have been fully considered, but have not been found convincing.

Applicant contends that the Office improperly uses Schulte2 as extrinsic evidence to show what one of ordinary skill in the art would understand Clemetson to disclose at the time of the invention. Schulte2 is not prior art and therefore cannot reflect what the skilled artisan knew at the time of the invention. Applicant submits that Schulte2's conconclusion was made in reference to the antibodies studied, namely JAQ1, JAQ2, and JAQ3, rather than literally all anti-GPVI agents. Further, Applicant submits that such conclusion should be limited to the activities of those antibodies addressed in Schulte2 and does not support the Office's position of inherency of the property of receptor down-regulation for all anti-GPVI agents. Applicant submits that Clemetson does not teach irreversible inactivation or degradation of a collagen receptor.

Contrary to Applicant assertions and arguments Clemetson's antibodies would have the claimed feature of irreversible inactivation or degradation of a collagen receptor on thrombocytes in the absence of evidence to the contrary as is evidence by Schulte that anti-GPVI agents, irrespective of their binding site may generally induce down-regulation of the receptor in vivo (see abstract in particular). The Examiner notes that Schulte uses the term "generally", therefore Schulte is referring to anti-GPVI antibodies in general not only the antibodies studied.

13. Claims 1-2, 4 and 11-12 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 6,245,527, as is evidenced by Schulte et al (Blood, 15 May 2003, Vol. 101, No. 10, pp. 3948-3952) for the same reasons set forth in the previous Office Action mailed 11/17/04.

Applicant's arguments, filed 5/12/05, have been fully considered, but have not been found convincing.

Applicant refers to the arguments regarding Schulte2 above. Further, Aplicant submits that Busfield does not address the concept of irreversible inactivation or degradation of a collagen receptor on thrombocytes and therefore, does not teach every element of the rejection claims.

Contrary to Applicant assertions and arguments Busfield's antibodies would have the claimed feature of irreversible inactivation or degradation of a collagen receptor on thrombocytes in the absence of evidence to the contrary as is evidence by Schulte that anti-GPVI agents, irrespective of their binding site may generally induce down-regulation of the receptor in vivo (see abstract in particular). The Examiner notes that Schulte uses the term "generally", therefore Schulte is referring to anti-GPVI antibodies in general not only the antibodies studied.

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1 and 5 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nieswandt *et al*, in view of Owens *et al* (1994) (IDS Ref. C58) for the same reasons set forth in the previous Office Action mailed 11/17/04.

Applicant's arguments, filed 5/12/05, have been fully considered, but have not been found convincing.

Applicant argues that Nieswandt is not prior art against the instant application and therefore cannot be used as a basis for rejecting the claims. Applicant further argues that Owens contains no teaching of active principles that irreversibly inactivate or degrade a collagen receptor.

However, the cutoff date is based on 1-year time, which is measured from the U.S. filing date rather than a foreign filing date. Applicant is reminded that a rejection under 35 U.S.C. 102(b) cannot be overcome by foreign priority dates, outside the 1-year grace period measured from the U.S. filing date.

16. Claim 6 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Nieswandt *et al*, or US Pat. No. 6,245,527 each in view of U.S. Patent No. 6,406,888 (IDS Ref No. A) for the same reasons set forth in the previous Office Action mailed 11/17/04.

Applicant's arguments, filed 5/12/05, have been fully considered, but have not been found convincing.

Applicant submits that no combination of these references render claim 6 obvious. Applicant refers to the arguments under 102 rejections , that Nieswandt is not prior art against the instant application. Clemetson and Busfield, neither of these reference teach the concept of an anti-GPVI monoclonal or polyclonal antibodies that bind the epitope of the JAQ1 monoclonal antibody. Regarding Conklin, the patent does not teach anti-GPVI antibodies at all.

However, the cutoff date is based on 1-year time, which is measured from the U.S. filing date rather than a foreign filing date. Applicant is reminded that a rejection under 35 U.S.C. 102(b) cannot be overcome by foreign priority dates, outside the 1-year grace period measured from the U.S. filing date. Regarding applicant comments with respect to Busfield's antibodies does not binds the epitope of the JAQ1 monoclonal antibody, however, the referenced antibody binds GPVI and has the same function as JAQ mAb, therefore, binding to the same epitope is considered an inherent property of the referenced antibody in the absence of evidence to the contrary.

17. The following new ground of rejection is necessitated by the IDS submitted 5/12/05.

18. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clemetson *et al* (IDS ref No. 6) in view of in view of U.S. Pat. No. 6,413,755 and further in view of Harlow.

The teachings of Clemetson *et al* reference have been discussed, supra.

The claimed invention differs from the reference teaching only by the recitation of a method of preparing a medicament agains tthrombotic disease comprising an antive principle that induces an irreversible inactivation of degradation of a collagen receptor on thrombocytes in combination with a pharmaceutically acceptable carrier in claim 11, wherein the at least one active principle is a monoclonal antibody in claim 12.

Harlow *et al* teach a method of producing monoclonal antibodies comprising immunizing an animal (i.e. a mouse) with a protein or portion thereof (i.e. fragments), harvesting spleen cells from said animal, fusing said spleen cells with myeloma cell line, and culturing said fused cells

(i.e hybridoma) under conditions that allow production of said antibody. Harlow *et al* further teach that the monoclonal antibodies stems from their specificity, homogeneity and ability to be produced in unlimited quantities (see pages 141-157 in particular).

The '755 patent teaches that any compounds identified can advantageously be used as a medicament or in the preparation of a medicament. Alternatively, the compounds can be included in a pharmaceutical composition together with a pharmaceutically acceptable carrier (see col., lines in particular).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to produce monoclonal antibody using the method taught by Harlow et al with the immunogenic fragment taught by Clemetson *et al* and include them in the preparation of a medicament taught by '755 patent.

One ordinary skill in the art at the time the invention was made would have been motivated to do so because the monoclonal antibodies produced exhibit a high degree of specificity and great affinity as taught by Harlow and because the medicament would be used in a method of treatment.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expection of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

19. No claim is allowed.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher Haddad, Ph.D.
Patent Examiner
July 6, 2005

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600